DEPARTMENT OF THE ENVIRONMENT

GOVERNMENT RESPONSE TO THE SEVENTH REPORT OF THE HOUSE OF LORDS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY, 1992–93 SESSION

Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness

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Government Response to the House of Lords Select Committee on Science and Technology Report on Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness

Introduction

1. The Government welcomes this timely and detailed report from the Select Committee on how regulation of biotechnology affects the competitiveness of United Kingdom industry. The section of the enquiry dealing with the difficult issue of public understanding and acceptance of this fast moving technology is also welcomed.

2. The Government believes that modern biotechnology has far-reaching implications for the UK economy and will have a major impact on products and processes across a wide range of sectors. It is a key enabling technology which has the potential to enhance significantly the competitiveness of many sectors of British industry. The Government recognises the need to get both an appropriate regulatory framework and the right climate for investment to enable UK industry to remain competitive. Sensible regulation is crucial and, in line with Government policy, should be founded on the best scientific evidence available and be proportionate to any risk involved.

Part I

3. The Government considers that the regulatory system now existing in the UK leaves industry well placed to compete in global markets but recognises that industry has not always shared this perception. However, rapid evolution has taken place in biotechnology regulation in the UK and elsewhere over the past few years, resulting in the introduction of fast track procedures for clearance of some deliberate releases of genetically modified organisms (GMOs) and simplification of notification procedures governing the contained use of GMOs.

4. Such evolution in regulation was foreseen as long ago as 1989 by the Royal Commission on Environmental Pollution (RCEP) in their thirteenth report, "The Release of Genetically Engineered Organisms to the Environment"[1], and was provided for in the tiered controls introduced in Part VI of the Environmental Protection Act 1990 (EPA). It has been and will remain an important aspect of Government policy.

5. Similarly, the evolution from process- to product-based regulation of GMOs, which the Committee supports, was foreseen during the drafting of the two relevant EC directives. The Government has been at the forefront of discussions in Brussels to ensure that GMO products are regulated together with equivalent products derived by conventional means. The safety criteria applied to these products should not be affected by the way they are subjected to regulation. The Government will continue to press in the European Community for the evolution from GMO regulation to a product-based approach where this is practicable.

6. The recent measures to reduce burdens on industry without compromising protection of human health and safety and the environment have only been possible as a result of the rapidly expanding body of objective scientific evidence pointing to the safety of many types of GMO operations. This could only come through experience with the technology. The Select Committee enquiry coincided with this period of transition not only of the regulatory regime but also while the relevant UK industry was becoming familiar with the new arrangements.

7. The Government agrees with the Committee that public acceptance is of pivotal importance in the marketplace. It is, of course, by no means certain that biotechnology products will ultimately gain public acceptance simply because they are desirable and reliable, they will also need to be perceived to be safe and to be successfully marketed.

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[1] Cm 720, HMSO

8. To address the need for regulatory scrutiny and public reassurance, the UK regulatory bodies, guided by the Advisory Committee on Genetic Modification (ACGM) and the Advisory Committee on Releases to the Environment (ACRE), have aimed at designing and maintaining legislative controls that balance the need for safety and public reassurance with the minimum of restraint on industry and researchers. Evolution of controls in a rapidly developing area of technology is an inevitable and desirable consequence of increasing knowledge and the advisory committees continue to provide Government with up to date advice on such matters. Drawing on such advice, the Government will continue to review the regulation of GMOs to ensure that not only are human health and safety and the environment fully protected but also that this is achieved with the minimum burden on industry and the research communities. The Select Committee inquiry too has been a valuable stimulus and contribution to this process.

9. Because the need for a flexible approach to regulation in this field was anticipated from the outset, the Government is able not only to endorse but also to implement the great majority of the recommendations in the report. The following detailed response follows the order of the Recommendations (Section 7) of the Select Committee's Report.

PART II
Specific Recommendations

The recommendations in italics refer to Chapter 7 of the Select Committee's Seventh report in the 1992-93 session and are referred to by number. Where necessary, the recommendations have been grouped to make clearer the Government response.

General

7.1 The benefits of biotechnology are already well proven; biotechnology and products of biotechnology are with us to stay; and these products are likely to yield enormous future benefits to mankind.

7.2 Biotechnology is a growth area and United Kingdom scientists and industry are good at it.

10. Agreed. Beyond the many benefits of biotechnology which are already well proven, the "new" biotechnology of genetic modification promises yet more benefits that make that aspect of the technology well worth pursuing: for example, in innovative health care, in new approaches to developing agriculture and in improved environmental management and sustainable use of natural resources.

11. In recognition of this potential, the Government announced in the May 1993 White Paper, "Realising Our Potential; A Strategy for Science, Engineering and Technology"[1], its intention to create a new Biotechnology and Biological Sciences Research Council (BBSRC), which will come into being on 1 April 1994. The new Council will shortly receive its Royal Charter, which gives it a clear mission statement, placing special emphasis on meeting the needs of users of its research and training output. The creation of the new Council will serve to strengthen the already strong biotechnology science base which exists in the UK. The Government's intention not only is to ensure that United Kingdom scientists and industry remain "good" at biotechnology, but to create a favourable climate for them to get even better at it.

7.3 In all areas where biotechnology has applications people should be able to exploit its economic benefits subject only to such regulation as may be necessary to meet identifiable disbenefits, especially to preserve safety.

12. The Government is committed to creating the best climate for industry to develop the outputs of research, including that from the BBSRC. The Government agrees that the economic benefits of applications of biotechnology should be

[1] Cm 2250, HMSO

exploitable where these meet appropriate safeguards. Potential disbenefits which need to be considered include those to human health and safety and the environment. Environmental impacts are not easily rectified after the event and environmental risks need to be evaluated in the context of potential benefits.

13. The present system of regulation also plays an important part in underpinning public confidence that biotechnology is controlled adequately. This need for public reassurance was clearly identified by the Royal Commission on Environmental Pollution (RCEP) in their thirteenth report, "The Release of Genetically Engineered Organisms to the Environment". In line with the recommendations in this report however, regulation is, and must continue to be, based on objective criteria and scientific assessment of any risk involved. The market place should be left to decide the commercial success of individual applications.

7.4 Early fears about GMOs in contained use turned out to be unfounded. As a general principle, except where pathogens are involved, existing laboratory (GMP) and industrial (GILSP) practice provide sufficient safeguards under the purview of institutional biosafety committees. Except where pathogens are involved separate regulation of GMOs in contained use is unnecessary.

14. Based on the most up to date scientific advice of the relevant advisory committees, the Government agrees with the Select Committee that the risks associated with the use of GMOs in contained use, particularly to human health, are now seen to be much smaller than may once have been anticipated.

15. There are two main reasons for this: the events that would have to take place at molecular level for a modified organism to acquire unintended novel harmful properties have been shown to be unlikely; and where GMOs are known to be hazardous there is growing confidence that these are controllable in contained facilities, and, indeed, that organisms can be selected so that they are unable to survive except in the special environment of the experiment or process.

16. Less is known about the risks to the environment than about risks to human health, partly because of the complexity of the environment and partly because there is less experience. Environmental protection is an important consideration in evaluating the safety of GMOs in contained use because of the possibility of escape. Nevertheless, as for human health, as more has become known about GMOs, many of the risks posed to the environment have come to be seen to be smaller than first thought and it now appears clear that much of the work with GMOs in containment poses little or no risk to the environment.

17. Consequently, the Government agrees with the Select Committee that good laboratory or industrial practice provides sufficient physical safeguards for the contained use of GMOs which are not pathogenic (ie are not harmful to humans or the environment). In fact as regards physical safeguards the regulations do not require more than that. What separate regulation there is for non-pathogens is chiefly concerned with the advance notification of industrial processes. In line with the Select Committee's recommendation the case for relaxation of this is already being pursued by the UK Government in the Committee of Competent Authorities set up under EC Council directive 90/219/EEC[1].

7.5 With a few exceptions involving bacterial or virus vectors, live vaccines, or modification of the genome of animals (which should continue to be monitored by ACRE), deliberate release of GMOs is not inherently dangerous.

18. The Government broadly agrees. Experience with GMOs in the United Kingdom and elsewhere has proved that, in many cases, the deliberate release of GMOs is not inherently dangerous and this view is reflected in recent moves to reduce the regulatory burden on certain types of GMO release. Such moves were anticipated by the RCEP in their thirteenth report and in subsequent Government policy statements.

19. Following advice from the Advisory Committee on Releases to the Environment (ACRE), the Government agreed in October 1993 a new scheme for

[1] EC Council Directive 90/219/EEC on the Contained Use of Genetically Modified Microorganisms

"fast-track" procedures for low-hazard and low-risk GMO crop plants. The first tranche of releases qualifying for this scheme were announced in January this year. ACRE has a statutory duty to advise on all releases, but the Government is keen to ensure that ACRE is able to focus its attention on unfamiliar or higher risk releases. The low risk releases of GMOs dealt with under fast track procedures are those for which ACRE has already given generic advice. ACRE, together with the Department of the Environment, will regularly monitor the GMO releases included in the fast track. In this way, additional release categories may be incorporated into the scheme, or if necessary removed from it, in the light of developing experience.

7.6 In framing the Directives on which the United Kingdom regulations are based the European Commission took an excessively precautionary line which, in terms of scientific knowledge, was already out of date when they were being prepared in the late 1980s. Advice to that effect appears to have been ignored.

20. Biotechnology is a fast-moving technology and it is therefore appropriate that legislative and administrative controls regulating the use of GMOs are in a state of continuing evolution. As scientific experience accumulates, regulations will be reviewed and tightened or loosened as is appropriate to risk. It is therefore no surprise that the Select Committee views some of the detailed provisions of the two EC directives governing the use of GMOs now to be dated and the Government agrees with this view. However, notable progress has been made in revising aspects of each directive in recent months, and the Government is committed to continuing to pursue the development of European legislation in line with the best scientific advice available.

21. The Government will consult widely on future proposed amendments to regulations controlling biotechnology products, as it has in the past.

7.7 It is vital for the future development of biotechnology regulation that Commission policy be coherent and the work of the Biotechnology Co-ordinating Committee is essential to that process.

22. The Government considers that it remains important for European policies on biotechnology to be co-ordinated effectively. The role of the European Commission is, of course, central to this task and the Government is confident that the Commission will note the view expressed by the Select Committee on the work of their Biotechnology Co-ordinating Committee.

Contained use

7.8 The classification of pathogenicity of organisms and scale of activities as the basis of risk assessment in the contained use Directive is fundamentally unscientific. The Government should press for amendment of the EC Directive to substitute a risk assessment system in place of the present classification.

23. The Government agrees that a scientifically based risk assessment system is key to the regulation of contained use of GMOs but does not share the view that the classification system used in the contained use regulations is fundamentally at odds with this maxim. The present criteria for the classification of organisms and, with the few exceptions identified at paragraph 27 below, the activity classification criteria, are derived from risk assessment principles. They are an attempt to identify the elements of a GM activity that contribute to the risk, and express them as criteria which will be determinant enough to act as triggers for notification procedures. They are not themselves the "basis of risk assessment".

24. Taking a standard risk assessment approach, the criteria for classification of organisms and activities distinguish between the hazard (the potential for harm - here mainly associated with the properties of the modified organism) and the likelihood that harm will actually result (mainly to do with the activity in which the organism is used).

25. There is no "risk assessment system" that is different in principle from this, or that would not analyze into the same elements. Some commentators have had in mind the risk assessment method developed by the Advisory Committee on Genetic

Modification (ACGM) and widely used in the UK. This is a procedure which systematically examines organism properties and derives a numerical rating to aid in the choice of control measures. It does not consider the nature of the activity and is ill-suited to the quite different purpose of triggering notification.

26. There are important defects in the criteria presently described in directive 90/219 which have led to some of the criticism voiced to the Select Committee. The organism criteria are lengthy, difficult to use and imprecise. They are derived from an OECD system intended for application to large-scale processes, and do not work satisfactorily when applied to small-scale or laboratory activity. Work on a revision to remedy these defects has begun in the Committee of Competent Authorities under directive 90/219. Amendments can be made relatively speedily as this part of the directive can be altered by means of the Article 21 procedure for adaptation to technical progress.

27. Some of the activity criteria, those connected with general purpose, are indeed unrelated to risk, and have led to unjustifiably disparate treatment for activities that differ solely in that, for example, one is making something for sale and the other for the purpose of research. The Government accepts the need to press for refinement of the criteria, though they are contained in the body of the directive and cannot be altered as readily as those dealing with organism properties.

7.9 Pending restoration of a risk-based system, under the current contained use regulations the use of safe (Group I) organisms should be subject only to notification whatever the scale of operations.

28. The Government agrees that the use of low hazard (Group I) organisms should be subject only to notification whatever the scale of operations, taking "notification" here to mean notification as work begins or by means of annual returns, as distinct from notification in advance. The case for amendment of the directive on this point is being pursued initially in the Committee of Competent Authorities (see also paragraph 17).

7.10 Whenever possible HSE should aim to give specific consents for contained use of unsafe (Group II) organisms well within the 90 day maximum.

29. Agreed. In fact, this is already done; a target has been set under which 80% of these applications should be processed within 30 days.

7.11 HSE should consult with patent authorities and issue early guidance on what period they consider reasonable for withholding commercially sensitive information from disclosure.

30. Agreed. The term "for so long as it is necessary" is indeed "interpreted sensitively in a way which does not preclude patentability", as the Select Committee advises *(paragraph 6.21)*. Consequently, the Health and Safety Executive does not set a limit to this period. Instead, sensitive information is withheld as long as it is sensitive. The patent authorities were closely involved in the preparation of the regulations on this point.

Deliberate Release

7.12 The Deliberate Release Directive should be amended to enable certain activities, selected by a group of EC national experts, to be subject to a vastly accelerated and simplified procedure of notification along United States lines.

7.13 Meanwhile, as a matter of priority, the United Kingdom should press the EC Commission to make the questionnaire specific to the type of organism, possibly under the original Directive's provision for "streamlining".

7.14 Applications under the existing regulations should be processed in not more than 30 days.

31. The Government has long held the view that accelerated and simplified procedures for certain categories of GMOs would eventually become appropriate. This was foreseen by the RCEP in their thirteenth report, is provided for in the flexible controls under Part VI of the Environmental Protection Act 1990 and

featured in the anniversary reports to the 1990 Environment White Paper, "This Common Inheritance; Britain's Environmental Strategy"[1]. In fact, a tiered scheme for handling consents was introduced last year, as foreseen in the Second Year Report to the White Paper. No amendment either to the parent EC directive (90/220/EEC[2]) or to the UK regulations was necessary to allow for this simplification.

32. Although the statutory time period for consideration of consent applications is 90 days, applications have been dealt with within an average of 60 days. But this will be bettered by moving to three tiers. "Fast-track" consents are dealt with within a maximum of 30 days, "streamlined" within a maximum of 50 days and "standard" consents within a maximum of the statutory 90 days, excluding any extra time required to gather additional information. Streamlined and standard consents are considered on a case-by-case basis by ACRE, with standard applications being discussed in committee.

33. Fast-track procedures are now applied to a range of low-hazard and low-risk GM crop plant releases. Addition of new organisms, whether these are plants, microorganisms or animals, and of new organism/ trait combinations, to the scheme is a relatively simple process. In the light of experience, ACRE gives generic advice to the Secretary of State for any new release category which they consider is appropriate to be added to the approved list. As soon as the advice is accepted and made public, new releases in these categories will be handled under the fast track. A significant proportion of crop plant releases will fall under the umbrella of fast-track and the system is easily adapted in the light of experience (see also paragraphs 58 to 60).

34. Of the releases which do not yet qualify for fast-track procedures, many are already dealt with under "streamlined" procedures. The 50 day maximum for dealing with these applications is a significant gain on the statutory 90 day limit.

35. In addition to the introduction of the tiered approach, and in a further effort to reduce the burden of information requirements on proposers to release GMOs, ACRE presented advice to the Secretary of State for the Environment earlier this year about which of the questions in current regulations are relevant to releases of genetically modified plants. Applicants for such releases need now only respond to these questions.

36. Notwithstanding the introduction of accelerated procedures in the UK, the Government is also pursuing further simplification in the European Community which is already foreseen within directive 90/220. In October last year, Member States unanimously agreed criteria for genetically modified plants against which requests for "simplified procedures" are judged, and the UK submitted a request in December last year for a "simplified procedure" to allow one consent to cover the release of more than one genetically modified arable or forage crop species at more than one site.

37. Finally, technical adaptation of specific annexes to the directive is possible. The Government is continuing to support moves in the Competent Authorities meetings towards the adaptation of the directive to technical progress by creating organism-specific information annexes. This will reflect the extent of the experience gained. The first such annex, specific for crop plants, was agreed by Member States in February of this year.

7.15 Universities and research councils should be exempt from paying fees on applications.

38. The Government's policy is to operate full cost recovery for consent schemes such as that for the deliberate release of GMOs, and not to differentiate between different types of applicant. The fee reflects the degree of scrutiny likely to be required.

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[1] Cm 1200, HMSO

[2] EC Council Directive 90/220/EEC on The Deliberate Release of Genetically Modified Organisms to the Environment

39. However, provision has been made in the existing scheme for different levels of fee, depending on the experience that has been gained with a particular type of GMO and therefore on whether it will qualify as a standard, streamlined or fast track case. The majority of applications for consents to release have been to release relatively familiar GMOs (streamlined cases), which attract a much reduced level of fee. Costs are further reduced if a single consent covers a programme of work extending over a period of years and several release sites.

7.16 No case can be made for the universal generic labelling of GMO derived foods or food constituents. The Food Advisory Committee should reject calls for such labelling.

40. The Food Advisory Committee issued a consultation paper on the labelling of genetically modified food in April last year and considered responses to the consultation paper at its meeting in September. As well as the responses to the consultation exercise it also took account of the report[1] of the Committee on the Ethics of Genetic Modification and Food Use, chaired by the Reverend Dr John Polkinghorne, which was published on 20 September.

41. The Food Advisory Committee has subsequently advised that it would be unrealistic to label every food whose production has involved genetic modification. However, it accepted that there should be provision for choice in relation to those foods which raise ethical concerns for a significant proportion of the population. It has therefore proposed that a GM food should be labelled if it:

a) contains a copy gene originally derived from a human;
b) contains a copy gene originally derived from an animal which is the subject of religious dietary restrictions; or
c) is plant or microbial material and contains a copy gene originally derived from an animal.

42. This labelling requirement would not apply if the inserted copy gene had been destroyed by processing and was not, therefore, present in the food.

43. The Government has accepted this advice and will seek provision on these lines in the proposed Novel Foods Regulation which is currently under discussion in Brussels. Since very few GM foods have yet come to the market, none of which contains viable GMOs, and public reaction to the technique is difficult to anticipate, provision for a review in a few years time will also be sought.

Process Regulation and Product Regulation

7.17 Wherever a GMO derived product is not viable and can be fully characterised (fully described) it should be subject only to a sectoral regulatory regime under existing product legislation. There is no case for labelling a GMO derived product differently from the same type of product not so derived. Evolution from process-based to product-based regulation should be accelerated rapidly. A single tier of regulation should be maintained. For the future, new product based Directives should include GMO derived versions as a matter of routine.

44. The Government agrees that non-viable GMO derived products, that is those which do not consist of, or contain, live GMOs, are appropriately regulated under existing product-specific provisions. Existing GMO legislation controls only products which consist of, or contain, viable GMOs. It is not intended to broaden the scope of this legislation to encompass non-viable products.

45. The Government has already made clear the need for evolution to product-based Community instruments in its response to the RCEP's thirteenth report, and is of the view that this step will help reduce burdens on industry. Government is therefore pleased to see this line endorsed in the Select Committee's report.

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[1] "Report of the Committee on the Ethics of Genetic Modification and Food Use" HMSO ISBN No 0 11 2429548, price £7.95

46. In the European Community, the UK Government has pressed consistently for product directives to cover GMOs and the need to avoid dual notification under process-based and product-based legislation. Any product covered by other EC legislation which contains a risk assessment similar to that in the Deliberate Release Directive will be subject only to the product legislation. To date, two Community product instruments[1] have been adopted, and several others are well advanced. The Government will continue to press for product-based instruments in Brussels.

7.18 Process-based regulation on present lines should be retained for research and development in those limited areas where regulation is required - that is to say all work involving pathogenic (Group II) organisms, and for deliberate release of GMOs outside the low to negligible risk category.

47. The Government agrees that process-based regulation needs to be retained for research and development in areas where it is required. Risks and safeguards for research and development work and for manufacturing processes do not divide naturally into product categories.

48. None of this is to say that GMO-specific regulation cannot be gradually relaxed. Paragraphs 17 and 26 to 28 deal with steps already being taken in that direction for contained uses and paragraphs 31 to 37 for deliberate release.

7.19 Work on further process based EC Draft Directives should cease forthwith; and the "Fourth Hurdle" of socio-economic need must not be introduced as an additional criterion in product regulation of biotechnology.

49. The Government wishes to see regulation develop so that safety is maintained without imposing any unnecessary burden on UK industry. Government is not aware of any further process-based EC draft directives addressing biotechnology safety. These would neither be necessary nor welcome since, from the regulatory viewpoint, product-based approaches to regulation are capable of providing identical information as process-based approaches.

50. It is vital that the process for the approval of biotechnology products is transparent, and based solely on the traditional criteria of safety, quality and efficacy. The Government has opposed, and will continue to oppose, the introduction of socio-economic criteria (the so-called "fourth hurdle") in the assessment of biotechnology products. The Government agrees fully with the Committee's rejection of the "fourth hurdle" since it is a subjective criterion which has the effect of second guessing the market and restricting consumer choice.

Regulation and Competitiveness

7.20 Regulation places United Kingdom biotechnology research and investment at a competitive disadvantage vis a vis our principal overseas competitors.

7.21 Implementation of the EC Directives on which the regulations are based is so uneven as to create inequalities even within the Community.

51. Balanced and proportionate regulation is fundamental to the UK's competitiveness in all industrial sectors. It follows that objective risk-based regulation of biotechnology will likewise be crucial to ensuring the success of those sectors on which it impacts.

52. At the time of the Select Committee hearings, regulations implementing EC legislation had only been in force in the UK for a matter of months, and the legislation had not been fully implemented throughout the Community. Against this background it would be premature to make meaningful international comparisons of the impact of regulatory regimes on industrial competitiveness. Nonetheless, the Government takes very seriously industry's perception that regulation places the UK at a competitive disadvantage and recognises the importance that perceptions play in investment decisions. UK regulation of GMOs

[1] EC Council Regulation (EEC) 2309/93 "The Authorization and Supervision of Medicinal Products for Human and Veterinary Use" and EC Council Directive 94/114/EEC, on "Enzyme and Microorganism Products Used in Animal Feedingstuffs".

is a flexible system, whereby applicants are able to reduce the information burden on themselves significantly as experience accumulates.

53. To address this perception and to avoid the real consequences for investment in biotechnology that this might have, Government has taken steps to make more transparent the already existing flexibility in the system. The new fast-track procedures for deliberate release were described in paragraphs 32 and 33.

54. The Government has also made more of the flexibility in the contained use regulations. Notably, guidance has been given to practitioners on how to notify connected programmes of work and how to update a notification to take account of developments in an activity. This has made it clearer that linked or evolving activities can be covered by a single notification and has helped notifiers to avoid unnecessary paperwork and cost. Other points of difficulty in interpreting and applying the regulations, revealed as they are put into practice, have been and are being dealt with quickly by means of circulars issued by the Advisory Committee on Genetic Modification.

55. Within the European Community, full implementation of the directives is not yet complete in all Member States. This has led to the creation of some inequalities within the EC. However, this situation should soon be remedied as the remaining countries implement. In the meantime, the regular meetings of the Committee of Competent Authorities help to ensure that questions of interpretation and implementation are addressed in a similar manner across the Community, and so contribute substantially to a level playing field.

56. The UK implemented each of the directives fully as appropriate, going beyond them only to follow the established UK practice of applying contained use provisions to organisms other than micro-organisms, but some Member States have imposed more onerous duties than the Contained Use Directive actually requires. This is possible due to the treaty base used to enact this directive - Article 130 of the Treaty of Rome. This too has caused inequality in the Community, but does not serve to disadvantage the UK.

57. The UK is committed to monitoring the situation closely within Europe, to ensure that EC regulatory requirements are fully and consistently implemented across the Community, to enable industry to take full advantage of the internal market.

58. The Select Committee went to some lengths to draw comparisons between regulations in the UK and in the US and Japan, though the comparative analysis of regulations in different OECD countries carried out for the Committee unfortunately did not include the UK. The Committee found that the approach taken in the US to biotechnology regulation was more flexible than that in the UK. The Government does not accept that this is the case. However, these are still early days in the implementation of the EC directives and it is too soon to make meaningful comparisons with regulations in other countries. The Government will continue to monitor the situation closely.

59. In general, the approach in the US has been to adapt already existing product-based regulations to the control of GMOs. In many cases, this has worked well, but there are inevitable gaps and overlaps. Some of this may be due to split competence between the Federal and State systems. The US authorities are in the process of adapting regulations, as well as introducing various new sets of regulations, to address these problems and, as in the UK, the US system is in a state of evolution.

60. The Select Committee paid particular attention to comparisons between the US and UK systems for regulating the deliberate release of GM crop plants. The US system was thought to be simpler and quicker than the system here. However, the recent introduction of fast track procedures has redressed the balance. The time taken to issue licences to carry out work is now the same in the US and the UK, but the Government believes the UK system is more easily adapted to change with accumulating experience.

61. Irrespective of approach, regulation influences both relative industrial competitiveness and international trade flows. It is true, as the Select Committee points out in *recommendation 7.22*, that issues other than regulation "are equally if not more important in determining competitiveness". Nevertheless, it is important for industrial competitiveness, for realising the full potential of global markets, and for unimpeded trade that regulatory obligations in the UK and our competitor countries remain broadly equivalent and at an appropriate level. To this end, the Government plays a lead role in international discussions on biotechnology regulation, in the Organisation for Economic Cooperation and Development and in the United Nations. International harmonisation of approaches to the risk assessment of GMOs will remain an important objective for this Government.

7.22 Non-regulatory factors like investment and intellectual property rights are equally if not more important in determining the competitiveness of United Kingdom biotechnology.

62. The Government agrees. Other factors are also important, for example, fostering the science base and the availability of qualified scientific manpower. These issues were recognised by Government in the May 1993 White Paper, "Realising Our Potential; A Strategy for Science, Engineering and Technology".

63. Similarly, whilst the effective adoption of biotechnology will become increasingly important to industrial competitiveness across a range of sectors, it will remain but one determinant of competitiveness. Other determinants, such as management, innovation, production efficiency, work skills, product quality and marketing will remain as relevant as ever.

7.23 Any regulations must be viewed critically, especially where they cannot be justified on scientific or public interest grounds and we recommend that the DTI's Deregulation Task Force reviews the contained use and deliberate release regulations on the basis of this report (if necessary with the assistance of BIGRAG) with a view to revising both the United Kingdom regulations and where necessary the parent EC Directives.

64. The Government recognises the necessity to keep under review the regulation of biotechnology in the light of increasing experience. As part of this process, the Deregulation Task Forces reviewed biotechnology regulations last autumn and have since published a number of recommendations. Some of these have already been accepted and action is being taken as described above. Other recommendations are being considered and/or followed up by the relevant departments. The new Deregulation Task Force will be monitoring progress in implementing these recommendations and will continue to keep these matters under review.

65. Subsequent review of regulations will continue to take place, as they have from the outset, in the Biotechnology Industry Government Regulatory Advisory Group (BIGRAG), taking into account the conclusions of both the Task Forces and the Select Committee. In particular BIGRAG is a valuable forum in which to develop the UK approach to revision of the contained use directive described in paragraphs 26 to 28.

Public Understanding

7.24 Promotion of public understanding is important but should not preclude the evolution of regulation.

7.25 Biotechnology products will ultimately gain public acceptance because they are desirable and reliable.

7.26 Education in schools is one of the most important methods of introducing familiarity with the concepts of biotechnology in the longer term.

7.27 In the short term, scientists and industry with the help of government have the chief responsibility for promoting wider public understanding of biotechnology by appropriate means.

7.28 DTI, in collaboration with MAFF, is the natural champion of this aspect of biotechnology and should ensure that public perceptions are based on reason and knowledge. DTI should respond positively to recommendations for action by BJAB.

66. The Government agrees with the Select Committee that the promotion of public understanding is important. The regulation of "new" biotechnology should be justified objectively and scientifically. This will help to encourage public confidence. Lack of public understanding does not justify unnecessarily restrictive regulations.

67. Public acceptance of biotechnology will ultimately hinge on the success of its products in the marketplace. This is a matter for industry. The conclusion of the Select Committee that biotechnology products will ultimately gain public acceptance because they are desirable and reliable is encouraging. It is by no means a foregone conclusion, however, that such products will automatically be commercially successful. Effective marketing is also important. An open, straightforward stance by industry will do much to influence public confidence.

68. Where Government is concerned, a number of separate initiatives (described below) address the understanding and awareness of biotechnology; these issues are best dealt with by the relevant government department and the Research Councils. The Government does not consider that such activities would benefit from further co-ordination, or that any one department is a natural champion of these aspects of biotechnology. Departments will, however, work together in areas of common interest.

69. The National Curriculum, introduced in 1988, (and its equivalent in Scotland) is the most important tool we have in schools for increasing pupils' understanding of science and technology and familiarity with concepts such as biotechnology. The Government agrees that the chief responsibility for promoting wider understanding of biotechnology rests with scientists and industry.

70. The White Paper, "Realising Our Potential; A Strategy for Science, Engineering and Technology", recognised explicitly that scientists need to learn to communicate more effectively with the public. This will be amongst the issues that the Office of Science and Technology will be addressing in their campaign on the public understanding of science. In line with the new missions for the Research Councils announced in the White Paper, the objects specified for the Councils in their Royal Charters will from 1 April this year include the promotion of public understanding in the relevant area of science. The Agricultural and Food Research Council (AFRC) has already introduced new activities designed to provide teachers and students with resource materials on biotechnology that complement existing resources and provide up to date examples of research and its applications. The formation of the Biotechnology and Biological Sciences Research Council (BBSRC) and the Research Councils' new focus on public understanding will add impetus to activity in this area. Further initiatives, including recommendations for action by the Biotechnology Joint Advisory Board will be considered once these new arrangements are in place. Meanwhile, building on the work of AFRC, a Consensus Conference on Plant Biotechnology will be funded by BBSRC and managed by the Science Museum. This conference, the first of its kind in the UK, will bring together members of the general public and experts to debate scientific issues publicly.

71. Government departments with regulatory responsibilities have an important role to play in providing balanced and impartial information to industry, consumers and the public in the areas which they regulate. As the Select Committee acknowledges, MAFF already produces a series of fact-sheets and is shortly to issue a single booklet providing factual information about biotechnology and its implications in the agriculture and food areas. It has also sought to provide information and stimulate discussion through the report on the ethics of genetic modification and food use and through consultation on the labelling of genetically modified food and other matters. The Government is always receptive to suggestions on ways to improve the provision of information.

72. The DTI has a complementary role in raising industry awareness of biotechnology, in particular in industries where the commercial potential of new and emerging technology is not yet well understood. The "Biotechnology Means Business" programme has already raised the awareness of over 500 companies to whom biotechnology may provide a competitive advantage.

73. The Government acknowledges the importance of public acceptance in determining the commercial success of biotechnology. All departments will keep a close watch over developments as the technology emerges on to the market place.

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